

Claims 1- 16 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of U.S.S.N. 09 / 515,732. In response, it is respectfully submitted that this rejection is now rendered moot. The '732 case now stands abandoned since no response was filed to the official action dated December 1, 2000 in that case. Withdrawal of the rejection is therefore respectfully requested.

Claims 17-18 were also provisionally rejected under the doctrine of obviousness-type double patenting in view of claims 1-6, 10, 15 and 16 of the '732 application. Based on the foregoing, it is believed that this rejection is now also moot and should be withdrawn.

Claims 1 – 8 were also rejected under 35 U.S.C. §112, first paragraph. In response, claim 1 has now been amended to simply make explicit what had been implicitly set forth. Thus, the inclusion of the word "poultry" in claim 1 is not intended to restrict the scope of the invention, since the subject vaccine is clearly intended for use with "poultry" (see page 2, lines 17-18). Withdrawal of the rejection is respectfully urged.

Claims 1, 7 – 13, 15, 16 and 18 stand rejected under 35 U.S.C. §102(b) for alleged anticipation in view of Wakenell et al.'s article in the American Journal of Vet. Research entitled "*Chicken embryonal vaccination with avian infectious bronchitis virus*". This rejection is respectfully traversed for the following reasons.

There is no anticipation because Wakenell et al. do not describe a vaccine which is not serially passaged. Instead, the reference seems to *mandate* serial passaging in order to effectively reduce pathogenicity. For at least these reasons, the reference cannot be held to anticipate the pending claims. Withdrawal of the rejection is therefore respectfully urged.

Claims 2-6, 14 and 17 stand rejected under 35 U.S.C. §103 (a) for alleged obviousness in view of the aforecited Wakenell et al. article. This rejection is also respectfully traversed.

As their article clearly details, Wakenell et al. were stymied to find a suitable live vaccine against IBV for chickens. In fact, the authors expressly teach away from the present invention by declaring:

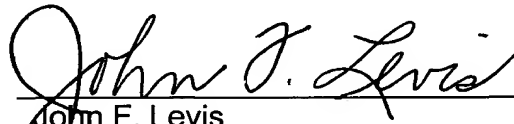
"V-IBV was found to be highly pathogenic for embryos, as measured by both hatchability and survival. . . Dilution of V-IBV from 10^5 -EID₅₀ to 10^2 -EID₅₀ did not significantly ($P > 0.05$) improve either hatchability (48%) or survival (0%)."

In other words, the authors predicted scant success in fashioning a vaccine as set forth by the present applicants. Instead, they chose to develop a vaccine by serially passaging a commercial product up to 40 times prior to final administration! Wakenell et al. were completely unaware that a vaccine and method could be developed as described by the present inventors. There is no teaching or hint in the reference that an IBV vaccine having the claimed characteristics could be formulated. The authors instead opted for a different path to vaccine development, one which apparently only reduced pathogenicity by tedious serial passaging.

For at least the foregoing reasons, Wakenell et al. cannot be construed as rendering obvious the presently claimed invention. Applicants therefore respectfully request withdrawal of the obviousness rejection under 35 U.S.C. §103.

The application is believed to be in proper condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Foley feel that any other point requires consideration, then she is cordially invited to contact the undersigned.

Respectfully submitted,


John F. Levis
Reg. No. 34,210

American Home Products Corporation
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Tel. No. (973) 683-2149

L:\PATENTS\AGSHARE\PAT\Levis\amendments\97023a1.doc

VERSION WITH MARKINGS TO SHOW CHANGES MADE

AMENDED CLAIMS:

1. (Amended) A process for protecting a host poultry animal, comprising administering a vaccine in ovo to a fertile egg containing an embryo of the host animal; and wherein the vaccine comprises an immunogenically-effective amount of a live, avirulent strain of infectious bronchitis virus, and further wherein the vaccine is not serially passaged through tissue culture.
13. (Amended) A process for protecting chickens from exposure to virulent strains of IBV, comprising administering in ovo to fertile chicken eggs a vaccine [comprising,] that is not serially passaged and comprises, on a per egg basis, an immunogenically-effective amount of a live, avirulent strain of infectious bronchitis virus.
15. (Amended) A vaccine for protecting chickens from exposure to virulent infectious bronchitis virus, wherein said vaccine is not serially passaged through tissue culture, comprising: a solution containing, on a chicken egg basis, a live avirulent strain of infectious bronchitis virus in an immunogenically-effective amount.